REMARKS

Applicant's attorney wishes to thank the Examiner for the telephonic interview conducted April 18, 2002 during which we discussed the Wang reference and possible discussion of the Wang reference in a Declaration of the present inventor.

Rejection Under 102(e) Over Wang et al.

Claims 1 and 5-8 have been rejected as anticipated by the Wang reference, U.S. Patent 6,124,007. Applicant respectfully traverses the rejection.

Applicant claims a method in which a laminate membrane having first and second adjacent thermoplastic layers is annealed at a temperature and time sufficient for a polymeric component to partially diffuse from one of the layers into the other. As demonstrated by the example on pages 27-28, a laminate annealed by the method of the invention exhibits a marked increase in its interfacial adhesion. In this example, the interfacial adhesion increased more than four-fold, from 4.0 p.l.i. to 17.6 p.l.i.

The Wang reference, on the other hand, is not concerned with whether its angioplasty balloon has any interfacial adhesion at all, and its methods of making the balloon do not appear to result in interlayer diffusion of the present invention. The Wang reference prepares its laminate by inserting one oriented tube into a second tube, which is oriented before or after the insertion. In the preferred method, described in the paragraph bridging pages 2 and 3, the first tube is stretched, then the first tube is inserted into the second tube, and finally the second tube is stretched to bring it into contact with the first, inner tube. The tubes are then expanded with

pressure and heat to make the balloon. This first method is described in some more detail in the first half of column 6, with the first tube being in particular the non-compliant [more rigid] material and the second tube being the softer, more compliant material. In the second method, a first tubing segment is stretched and blown in a mold, then a second tubing segment is stretched, inserted into the first tubing, and then the second tube is pressurized and heated to expand to "direct annular contact" to the first tube to form the laminate balloon. Column 3, lines 9-33. The Wang reference states that the layers of its balloon can be easily peeled apart after the manufacturing process. Wang reference, column 6, line 29-32.

Nor does the "annealing" described in the Wang reference inherently provide Applicant's claimed method for improving adhesion between adjacent layers. The balloon can be "provided with stepped compliance curves" by heating to shrink the balloon. Column 3, lines 34-38. The Wang reference's annealing is demonstrated in Example 8, where the balloon is "shrunk by annealing at 82° C. for 2 hours at 5 psi inflation pressure" to produce the stepped compliance curve of FIG. 7. [The reference to Example 9 in the Office Action appears to be a typing error, as that example does not appear to anneal the balloon.] As explained in the accompanying Declaration of Richard L. Watkins, the effect of this annealing appears to be only shrinkage of the outer balloon to provide mechanical compression of the inner, high modulus balloon.

In order for the interlayer diffusion of the present invention to take place, the laminate must be annealed at a temperature that is above the thermal transition temperature of the diffusing material. As the Declaration explains, the annealing temperature depends upon the particular materials of the laminate, their particular

compositions, molecular weight distributions, and endgroups, among other factors. The Wang reference annealing conditions obviously will not inevitably result in interlayer diffusion for all materials that might be selected for its tubes.

To anticipate an invention, a reference "must sufficiently describe the clamed invention to have placed the public in possession of it." *Minnesota Mining and Manufacturing Co. v. Johnson & Johnson Orthopaedics Inc.,* 24 U.S.P.Q.2d 1321 (Fed. Cir. 1992) [*3M*]. In *3M,* for example, a claim to an orthopedic casting fabric having particular thickness and mesh size parameters was not anticipated by disclosure in a prior reference of an orthopedic casting fabric that was a knit fiberglass. *Id.* at 1332. Even though the claimed parameters were "subsumed in [the prior reference's] generalized disclosure of knit fiberglass as a substrate," the prior reference "provide[d] no guidance as to how to construct a fiberglass cast with the beneficial properties achieved by the [claimed] invention." *Id.* While the prior reference's fiberglass *could* have the claimed thickness and mesh size parameters, from which the beneficial properties would necessarily flow, the prior reference was not "exact enough to identify" what the parameters were that would produce such beneficial properties. *Id.*

Similarly, the Federal Circuit held in *Ultradent Products Inc. v. Life-Like Cosmetics, Inc.,* 44 U.S.P.Q.2d 1336 (Fed. Cir. 1997) that a prior reference's disclosure of materials that might, with serendipity, be selected to fall within the claimed invention did not amount to an anticipating disclosure. The claim involved a material for bleaching teeth that had a matrix material having "sufficiently high viscosity" and being "sufficiently sticky" to have certain properties. *Id.* at 1341. The

defendant asserted that the claims were invalid as anticipated by a prior reference because increasing the percent of a material, carboxypolymethylene, in one of the patent examples produced the required properties. *Id.* The court ruled that even if the adjusted example provided the claimed viscosity and stickiness, "that does not mean that the claimed matrix material is necessarily described by the [prior] patent. . . . [T]here are many possible compositions that could be made within the range of carboxypolymethylene concentration (0.05% to 5%) that the [prior] patent discloses." *Id.* at 3141-42. To be anticipating, the prior patent must "describe to one of skill in the art the tested combinations, or other combinations meeting the limitations of the claims, from among the many possible candidates." *Id.* at 1342.

It is irrelevant to the issue of anticipation that one might unwittingly choose a particular combination of materials, decide in that particular instance to use the optional Wang annealing method, and unwittingly select a particular temperature and a sufficient duration that would allow for partial diffusion of a component from one layer into the other. The general disclosures of the Wang reference do not enable one to practice the present invention and inherently obtain those properties. "Before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is necessarily present in the reference." *SGS-Thomson Mircroelectronics, Inc. v. International Rectifier Corp.*, 32 U.S.P.Q.2d 1496, 1503 (Fed. Cir. 1994) (citing *Continental Can Co. USA Inc. v. Monsanto Co.* 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991)) (emphasis added). To be "necessarily present" the feature must *always* be present in what the prior reference describes. *W.L. Gore & Associates v. Garlock,*

Inc., 220 U.S.P.Q. 303, 314 (Fed. Cir. 1983) (no anticipation where the claimed product had a "unique nature" and the processes of the prior references would not always inherently "produce products meeting all of the claim limitations"). The skilled artisan, armed with all that the Wang reference discloses, would have no direction for improving interlaminar adhesion. The Wang reference simply does not teach the skilled artisan how to achieve that result.

Thus, an anticipating reference must enable one of ordinary skill in the art to select those embodiments that provide the particular advantage of the claimed invention when that advantage is not always available in practicing the prior reference's process. By the same token, a feature that is not always available in the prior process cannot be inherent in that process, for its enjoyment depends on a fortuitous selection of parameters that is not taught or hinted at in the reference. In the present case, as further explained in the accompanying Declaration, the Wang reference provides no direction for improving peel strength or interfacial adhesion of a laminate membrane. The Wang shrinkage does not mean that any diffusion into the adjacent layer has taken place, since the shrinkage is due to relaxation in the oriented layer. The Wang reference does not anticipate the present invention because it is not "at once specific and enabling with regard to the particular subject matter at issue." *In re Wilder,* 166 U.S.P.Q. 545, 548 (C.C.P.A. 1970)

Further, Applicants' process is not obvious from the Wang reference. There is no discussion in the Wang reference of improving interlaminar adhesion or any suggestion of how to increase interlaminar adhesion. It is not surprising that the Wang reference does not seek to improve its interfacial adhesion, as this reference is

mainly concerned with burst strength and compliance of its balloon for a one-use medical procedure of relatively short duration. Column 1, lines 23-26 & 37-45; column 2, lines 40-51. There is no need for the angioplasty balloon to have the durability and resistance to fatigue failure that a laminate membrane intended for other uses, such as bladders in athletic shoes, might require. See the present application, page 2, lines 1-9.

Applicant submits that, because the Wang annealing step is not inevitably carried out at a temperature above a thermal transition temperature of a layer component and is not inevitably carried out for a time sufficient for partial diffusion of the component into the adjacent layer, the Wang reference does not anticipate the method of the present invention. Further, because the Wang reference provides no direction on selecting materials and conditions that would allow such diffusion to occur, the present invention is patentable over the Wang reference. Accordingly, Applicant respectfully requests that the rejection be withdrawn. Reconsideration and allowance of the claims are respectfully requested.

Rejection Under 103(a) Over Wang et al. in View of Bonk et al.

Claims 1-29 have been rejected as unpatentable over the Wang reference, U.S. Patent 6,124,007, in view of the Bonk reference, U.S. Patent No. 6,082,025). Applicant respectfully traverses the rejection.

The shortcomings of the Wang reference have already been discussed. The Wang reference "annealing" conditions do not inevitably result in the diffusion of the

claims, and the Wang reference does not suggest under what conditions one might achieve such diffusion.

Because the Wang reference does not suggest annealing a laminate at a temperature above a thermal transition temperature of a polymeric component in its layers, it certainly does not suggest carrying out such annealing at least about 50°C above such a thermal transition temperature, or at least about 80°C above such a thermal transition temperature.

Applicant respectfully disagrees that the Wang reference suggests a bladder that is sealed and inflated after annealing, as alleged at the top of page 4 of the Office Action. It appears that the Wang reference only describes angioplasty balloons, and that such balloon are not sealed, but only temporarily inflated during the medical procedure.

There is no motivation to combine the Wang reference with the Bonk reference. The Wang reference concerns angioplasty balloons with layers that have been stretched and selected to increase burst pressure. Such balloon are inserted in blocked blood vessels and inflated to open the blockage. Wang, col. 1, lines 7-16. The Wang reference states, "These applications require extremely thin walled, high strength, relatively inelastic balloons of predictable inflation properties." *Id.* at col. 1, lines 16-18. The Bonk reference, on the other hand, concerns flexible, elastic membranes. *See, e.g.* Bonk, Title; col. 4, lines 56-63. The membranes are durable, meaning "that the membrane has excellent resistance to fatigue failure, which mean that the membrane can undergo repeated flexing and/or deformation and recover without delamination along the layer interfaces and without creating a crack that runs

through the thickness of the membrane." Bonk, col. 4, line 63 to col. 5, line 1. The microlayer polymeric composite layer of the Bonk reference has at least ten microlayers, and may have thousands of microlayers. Col. 7, lines 5-6 & 9-10. While the individual microlayers may be quite thin, col. 7, lines 19-22, the laminate may be 3 mils to 200 mils, col. 15, lines 4-6. Such a laminate would appear to be unsuitable as for the Wang reference angioplasty balloon, which has a single wall thickness of less than a mil. See, e.g., Wang, Example 1, col. 7, lines 26-27 (single wall thickness of 0.73 mil); Example 2, col. 7, lines 38-39 (single wall thickness of 0.3 mil); Example 3, lines 45-46 (single wall thickness of 0.43 mil).

Thus, the membranes of the Bonk reference appear to be unsuitable for the Wang reference angioplasty balloons. There would be no motivation for the person in the field of the Wang reference to select a membrane that is of unknown burst strength; too thick; and too elastic for his purposes, or on the other hand to look for membranes having durability and resistance to fatigue failure for a one-use surgical balloon. Further, the Bonk reference teaches to coextrude its membranes, *see, e.g.,* col. 17, lines 1-2, while the Wang reference excludes coextrusion of its membrane layers. The Office Action fails to explain why elasticity would be desirable in an angioplasty balloon that must be "relatively inelastic," Wang at col. 1, lines 16-18, or why it would be desirable to have very low gas transmission rates for a balloon that is inflated for only a short time and is never sealed to hold its inflation pressure. in fact, the attributes of the Bonk membrane are irrelevant to the properties needed by the Wang angioplasty balloon.

It might be within the realm of possibilities to make an angioplasty balloon with the Bonk materials, but that is not sufficient to make it obvious to do so, and would not seem to be desirable to do so. This does not even rise to an invitation to experiment, let alone a suggestion that such a modification would be desirable.

Neither the Wang nor the Bonk reference, either singly or in combination, teach or suggest a means of improving interfacial adhesion in a laminate; nor do they teach annealing a laminate at a temperature above a thermal transition temperature of a polymeric component for a time sufficient for interlayer diffusion to occur. Of equal importance is the fact that there is nothing in these references that would motivate the skilled artisan to make such combination and or to selection the particular conditions and materials of the claims without the benefit of hindsight.

In view of the deficiencies of the cited references, Applicant respectfully requests reconsideration and allowance of the claims.

The Examiner is invited to telephone the undersigned if it would be helpful for resolving any issue.

Respectfully submitted,

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